Food and Drug News . . .

Important Information for California Consumers and Food Processors

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Food and Drug Branch *Issue Number F-1-2001*

Food Labels

The goal of food labeling is to provide consumers with information that is factual and relevant. The food label allows consumers to compare one product to another, gives instructions for safe handling and storage, lists ingredients to help consumers select foods with ingredients they want or need to avoid, and identifies the firm responsible for the product.

Certain label information, such as the responsible firm's name and address and ingredient declaration, is required. Other label information such as health claims and terms that describe a food's nutrient content is voluntary. Additional mandatory label information has been added as the result of three federal laws that became effective in 1994: the Nutrition Labeling and Education Act of 1990 (NLEA), the American Technology Preeminence Act of 1991 (ATPA), and Dietary Supplement Health and Education Act of 1994 (DSHEA). The U.S. Food and Drug Administration (FDA) published a number of regulations implementing these three laws. California adopts all the federal labeling regulations, and has its own laws concerning additional labeling requirements. Regulations implemented under NLEA:

- require nutrition information on almost all processed foods,
- provide a new format for presenting nutrition information (i.e., "Nutrition Facts" panel),
- set definitions for nutrient content claims such as "low-fat",
- provide appropriate use of thirteen scientifically proven health claims, and
- require ingredient listing on all foods with two or more ingredients.

Under ATPA, food firms have to list the net contents of their products in both metric units and English (inch-pound) units. These changes are intended to make food label information more accurate and useful to consumers.

Dietary supplements are under different regulations from those for processed foods. The regulations implementing DSHEA (62FR 49826, 09/23/97; 65FR 999, 01/06/00):

- require dietary supplement products to carry a "Supplement Facts" panel with information similar to the "Nutrition Facts" panel that appear on most processed foods,
- set parameters for use of the terms "high potency" and "antioxidant," and for making the "structure or function" claims, and
- identify on the label the part of the plant used to make the product if it contains botanical ingredients.

Label Panels

A food package usually has at least two distinct areas: the principal display panel (PDP), and the information panel (IP). The PDP is the part of the label consumers see first when selecting a food product. Therefore, in most cases, the PDP is the front of the package. The IP is usually to the immediate right of the PDP (to the left, rear, top or bottom if there is insufficient space to the right of the PDP). The PDP is where information such as the name of the product and the net quantity of contents is located, while the IP is mainly reserved for nutrition information, the ingredient list, and the name and address of the responsible firm (manufacturer, packer or distributor). All required information on the label must be legible. It cannot be concealed in any manner such that it is unlikely to be read by the consumer. The size of the lettering, unless stated, must be at least 1/16 inch (there are exceptions for small, single-serving packages. Refer to 21 CFR §101.2 for details). All required information must be in English. Accurately translated information in another language may accompany it.

Labels must be made of materials that do not contaminate the food. If there is likelihood that the paper, ink or adhesive of a label will touch the

product or penetrate the packaging, these materials must be safe for food use.

Food Name

All foods must be named. This name, which is often called the "statement of identity," is either the "common name" of the food or a "fanciful name." If a fanciful name is used, it must be accompanied by a descriptive phrase at least 1/2 the type size of the product name. The name has to be truthful. If it is a "flavored" product, it must so state (e.g., "cherry flavored" pie). If the flavor is not derived from a natural source, then it must so indicate (e.g., "artificial cherry flavored" pie). When appropriate, it must describe the form of the food too, such as "-sliced peaches" or "whole peaches". A brand name can serve as the statement of identity if the name is commonly used and understood by consumers to refer to a specific food (e.g., Pepsi Cola, Coca-Cola).

Responsible Firm

There must be a firm identified on the label as a responsible party. The firm's name, city, state and zip code must be declared. If the firm is not in the current telephone guide for that city, the street address must also be listed. Beginning January 1, 2002, all labels of bottled water must bear bottler's or brand name owner's telephone number and address.

Net Quantity

Every packaged food must declare its count, net weight (drained weight if appropriate) or volume. The net quantity refers only to the quantity of food in a package or container. It includes the weight of any liquid in which the food may be packed if the liquid is usually eaten. It does not include the weight of the container or wrappers. It must be stated in both English (inch-pound) units and metric units. For example, Net Wt 8 oz (226 g).

Ingredients

All packaged foods composed of two or more ingredients (including standardized foods) are required to include an ingredient list. Foods with two or more discrete components (e.g., cherry pie that has filling and piecrust) may have a separate ingredient list for each of the components. For foods that are sold from bulk, a list of ingredients must be stated on a sign or on the food's original container. The ingredient declaration must be legible and be correctly listed in descending order of predominance by weight. Ingredients must be listed by their "common names." Certain ingredients require special declaration (for more information about the special declaration, see 21 CFR §101.4).

Product Dates

Certain foods [e.g., infant formula, dairy products, and potentially hazardous foods (PHF) that are in oxygen-reduced atmosphere or in containers that creates anaerobic conditions] are required to have an expiration date, while product dating is optional for other foods. There are two types of dating on food packaging: "open dating" and "code dating". In open dating, dates are stated alphabetically, such as "July 10", or numerically such as "7-10" or "710". In code dating, the information is coded in letters, numbers and symbols that only the firm (manufacturer) can translate. (See "Refrigerated Foods" below for the definition for PHF).

Open dating includes "pull date", "quality assurance or freshness date", "pack date" and "expiration date." Manufacturers have the pull date, quality assurance date or pack date on labels to inform retailers and consumers when the product was made or how long their products should be offered for sale or how long their products will be of optimum quality. Expiration date is the date before which a product should be eaten. Open dating is recommended for all foods that are readily perishable.

Code dating enables the manufacturer to convey a relatively large amount of information (such as production code and date, location of production and/or packaging) with a few small letters, numbers and symbols. In the case of recall, it makes it easier to quickly identify and track down the product and take it off the market.

Nutrition Labeling

Most processed and packaged foods (except exempt foods) must declare information about the foods' nutritional content using formats under the heading "Nutrition Facts" (see attached sample nutrition facts format). Variations in the format and criteria for the variations are defined in the regulations (21 CFR §101.9). For instance, certain foods may qualify for a simplified format. This format is allowed when the food contains insignificant amounts of seven or more of the mandatory nutrients.

The following foods, provided that they neither bear nutrition information nor make nutrient content claims or health claims on their labels, are exempt from the mandatory NLEA nutrition labeling requirements: food produced by

small businesses (the exemption applies to businesses with fewer than 100 full-time equivalent employees and products fewer than 100,000 units; Please refer to www.cfsan.fda.gov/~dms/sbel.html for details); restaurant food; ready-to-eat food prepared primarily on site; food sold by food service vendors and vending machines; food shipped in bulk as long as it is not for sale in that form to consumers; medical food and infant formula; and food containing no significant amount of any nutrients.

Nutrient Content Claims

Eleven basic terms have been defined for several nutrients, and FDA has set conditions for the use of these terms. The terms are: free, low, reduced, fewer, high, less, more, lean, extra lean, good source, and light. For example, the term "sodium free" means that the food contains less than 5 milligrams of sodium per serving of the food. (For details, please refer to 21 CFR §§101.13 and 101.25 to 101.69)

Health Claims

NLEA allows manufacturers to make certain claims linking the effect of a nutrient or food to a disease or health-related condition. FDA has approved the following thirteen claims and defined condition under which the claims can be used. The approved claims are:

- a diet high in calcium and a lower risk of osteoporosis (21CFR 101.72),
- a diet low in total fat and reduced risk of some cancer (21CFR 101.73),
- a diet low in saturated fat and cholesterol and reduced risk of coronary heart disease (21CFR 101.75),
- a diet rich in fiber-containing grain products, fruits and vegetables and reduced risk of some cancers (21CFR 101.76),
- a diet rich in fruits, vegetables and grain products that contain fiber and reduced risk of coronary heart disease (21CFR 101.77),
- a diet low in sodium and reduced risk of high blood pressure (21CFR 101.74),
- a diet rich in fruits and vegetables and a reduced risk of some cancers (21CFR 101.78).
- a diet rich in folate and reduced risk of neural tube defects (21CFR 101.79).
- a diet low in sugars and starches and less likelihood of tooth decay (21CFR 101.80).
- a diet rich in soluble fiber from certain foods and reduced risk of coronary heart disease (21CFR 101.81).
- soy protein and reduced risk of coronary heart disease (21CFR 101.82).
- plant sterol/stanol and reduced risk of coronary heart disease (21CFR 101.83).
- whole grain foods and risk of heart disease and certain cancer

(For details, please visit http://vm.cfsan.fda.gov/~dms/flg-6c.html)

Juice Products

FDA recently published a final rule to improve the safety of juice products by requiring processors to use HACCP principles for juice processing (66 FR 6137-6202, 1/19/01). Until HACCP programs are implemented, juice processors must continue to use the required warning label statement (63 FR 37029-37056, 7/8/98) for fresh fruit and vegetable juice products that have not been validated to show a 5-log reduction of pathogenic microorganisms.

Refrigerated Foods

California law requires that all potentially hazardous foods (PHF) have the statement "Perishable Keep Refrigerated" on the label in a conspicuous location, normally on the PDP. PHF is defined as food which is capable of supporting growth of infectious or toxicogenic microorganisms when held at temperatures above 45 degrees Fahrenheit. PHF does not include foods that have a pH level of 4.6 or below, a water activity value of 0.85 or less, or food products in hermetically sealed containers processed to prevent spoilage.

The statement "Perishable Keep Frozen" is also acceptable on the label of foods that are frozen.

Confectionery Products Containing Alcohol

If a confectionery product contains alcohol in excess of ½ of 1 percent by weight, the fact must be stated on the label for the food. If a facility sells directly to consumers such confectionery products that are unpackaged or unlabeled, the facility owner must provide a written notice to consumers of that fact (H&SC 110695, 113985)

Organic Foods

Foods represented as “organic” are currently required to bear a statement (or similar language): “Organically grown and processed in accordance with the California Organic Foods Act of 1990.” Recently, however, USDA finalized a rule entitled “National Organic Program” (65FR 80548, 12/21/00). The rule, which preempts the state

law, became effective on February 21, 2001 and requires that all organic foods comply with the federal requirements by August 21, 2002 (18 months from the effective date). Until then or the relevant California organic law is amended, organic foods sold in California may comply with either the existing California law or the USDA regulations. Anyone who has questions can contact any of the Food and Drug Branch (FDB) Offices.

Safe Handling Instructions

Raw meat and poultry products (fresh and frozen) including shell eggs must bear safe handling instructions on their labels. The handling instructions should address safe storage of raw product, prevention of cross-contamination, cooking of raw product, and/or handling of leftovers. For example, shell egg cartons are required to bear a statement "To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly" (65FR 76091, 12/5/00). Further, the California Uniform Retail Food Facility Law (H&SC Section 113997) additionally requires that retail egg containers be prominently labeled "Refrigerate after purchase" or a conspicuous sign be posted advising consumers that these eggs must be refrigerated as soon as practical after purchase. For detailed information on meat and poultry products, consumers can call the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS) Meat and Poultry Hot Line.

Other Label Declarations

There are many optional statements that can be made on a label. These include: storage and thawing information, directions for use, product pictures or vignettes, universal product code, trade marks and copyrights, and religious symbols.

Food Label Questions

If you have questions about labeling laws and regulations or feel that a label is misleading, please contact any of the FDB Offices.

FDB does not approve labels. For designing, formatting and proofing labels, a competent "food label consultant" should be retained. For questions regarding the labeling of foods containing more than 3 percent meat or poultry products, processors should contact the USDA-FSIS Meat and Poultry Hot Line or its Western Region. Information on labeling of foods to be imported or exported can be obtained from the FDA. The California Food and Agriculture Department's Milk and Dairy Foods Control Branch provides labeling information on milk and dairy products.

FDB Offices

South: 1449 West Temple Street, Room 224, Los Angeles, CA 90026
(213) 580-5719
North: 601 North 7th Street (MS-357), P.O. Box 942732
Sacramento, CA 94234-7320
(916) 445-2263

Other Agencies

FDA, San Francisco District Office, Compliance Branch
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
(510) 337-6700

FDA, Los Angeles District Office, Compliance Branch
1521 Pico Blvd
Los Angeles, CA 90015
(213) 252-7612

USDA-FSIS, Meat and Poultry Hot Line, 1-800-535-4555 or
(202) 720-3333.

USDA-FSIS, Western Region
620 Central Ave., Bldg. 2-C
Alameda, CA 94501
(510) 273-6255

California Department of Food and Agriculture, Milk and Dairy Food Control Branch,
1220 N Street,
Sacramento, CA 95814
(916) 654-0773

References

California Sherman Food, Drug, and Cosmetic Law §26500-26599 and §113700-114475 (CURFFL)

Title 21, Code of Federal Regulations (21 CFR), Part 100-109, April 1, 2000 (4/1/2000)

56 Federal Register (FR), 60880-60891, 11/27/1991

58 FR 2066-2941, 1/6/1993

58 FR 17085-17173, 4/1/1993

58 FR 17328-17346, 4/2/1993

58 FR 44020-44090, 8/18/1993

58 FR 60105-60109, 11/15/1993

59 FR 350-426, 01/04/1994

59 FR 24039, 5/10/1994

59 FR 24232-24250, 05/10/1994

62 FR 49826-49892, 09/23/97

63 FR 37029-37056, 07/08/98

65 FR 999-1050, 01/06/00

65 FR 76091-76114, 12/05/00

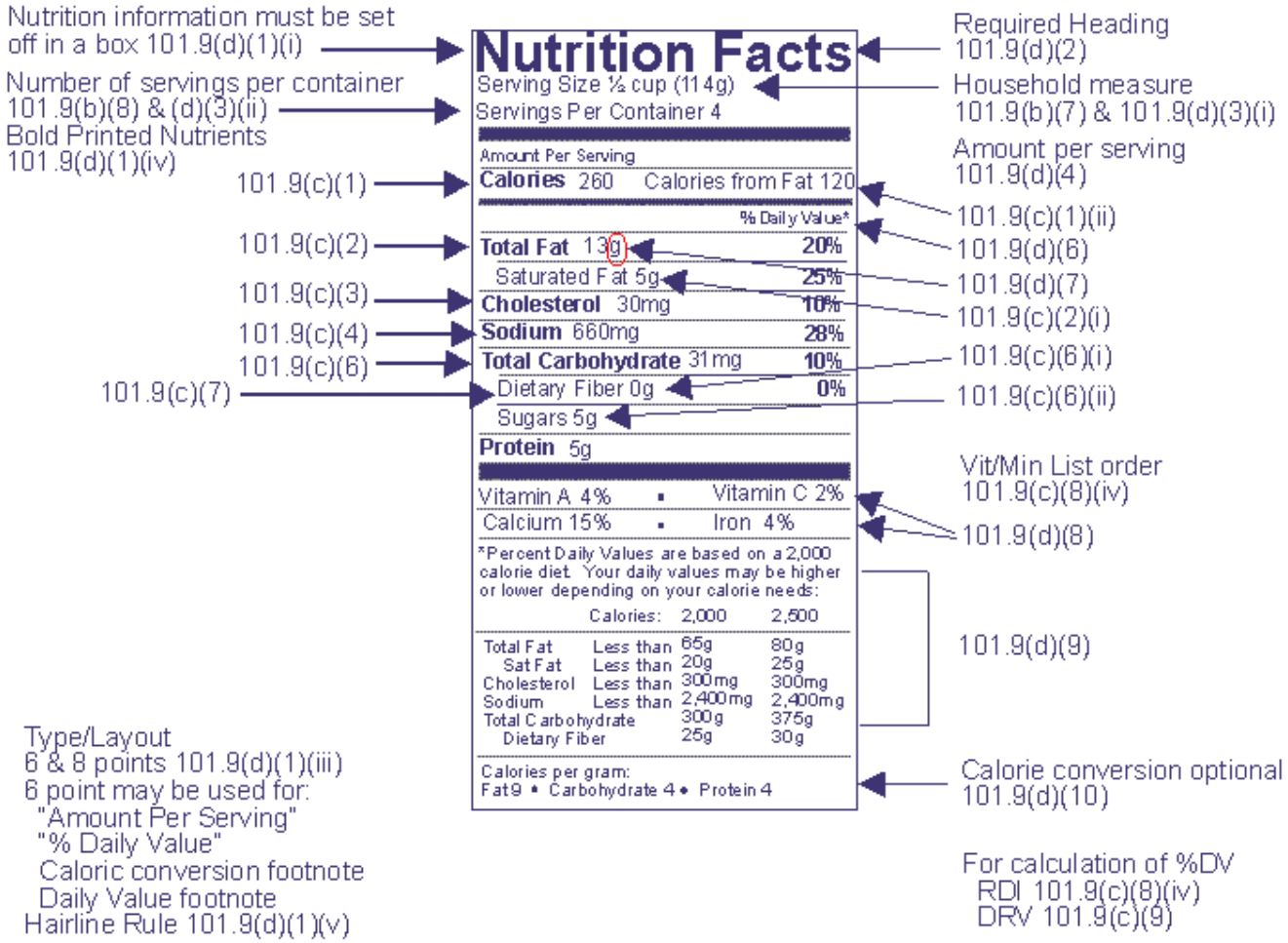
66 FR 6137-6202, 01/19/01

FDA Consumer, Food Label Close-up, Vol. 28 (3), 1994

A Food Labeling Guide, FDA, http://vm.cfsan.fda.gov/~dms/flg-2.html; http://vm.cfsan.fda.gov/~dms/flg-4.html; http://vm.cfsan.fda.gov/~dms/flg-6c.html; http://www.cfsan.fda.gov/~dms/nutrguid.html http://www.cfsan.fda.gov/~lrd/hhssupp2.html

How To Read The New Food Label, FDA and American Heart Association, FDA 93-2260

Sample Nutrition Facts Panel:



LABELING OF DIETARY SUPPLEMENTS:

Starting March 23, 1999, consumers will see more complete information on labels of dietary supplement products, including an information panel titled "Supplement Facts," a clear identity statement, and a complete list of ingredients.

The "Supplement Facts" panel will provide information such as the quantity of specific nutrients in vitamin and mineral products, and the part of the plant used in herbal products. It will be similar in format to the "Nutrition Facts" panel that appears on most processed foods.

Specifically, the "Supplement Facts" panel will show the following:
* The manufacturer's suggested serving size.
* Information on nutrients when they are present in significant levels, such as vitamins A and C, calcium, iron and sodium, and the percent Daily Value where a reference has been established -- similar to nutrients listed in the "Nutrition Facts" panel on food labels.
* All other dietary ingredients present in the product, including botanicals and amino acids -- those for which no Daily Value has been established. [For sample labels, see **http://vm.cfsan.fda.gov/~acrobat/hhssupp2.pdf**]

Herbal products will be identified by the common or usual name and the part of the plant used to make the supplement (such as root, stem or leaf). If the common or usual name is not listed in Herbs of Commerce, published by the American Herbal Products Association, the Latin binomial name such as Tercoma mollis.HBK or Cecropia obstusifolia Bert. will be listed.

All ingredients in the product will be declared in the ingredient statement or within the "Supplement Facts" panel.

A statement of identity will appear on the front panel of the product label. The statement must use the terms "dietary supplement" or a term identifying the contents of the product, such as "Vitamin C supplement" or "Herbal supplement."

The new labeling rule implements some of the major provisions of the Dietary Supplement Health and Education Act of 1994 (DSHEA). The rule was published September 23, 1997, with an effective date of March 23, 1999, giving industry 18 months to comply. Products labeled prior to March 23 can continue to be sold until stocks are depleted. Some companies have already introduced products with the new labels.

[Source of the Information above: http://www.cfsan.fda.gov/~lrd/hhssupp2.html]

SUMMARY OF NUTRITION LABELING RULES FOR DIETARY SUPPLEMENTS:

Dietary supplement containing dietary ingredient with and without RDI's and DRV's:

Supplement Facts

Serving Size 1 Packet

Amount Per Packet		% Daily Value
Vitamin A (from cod liver oil)	5,000 IU	100%
Vitamin C (as ascorbic acid)	250 mg	417%
Vitamin D (as ergocalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopherol)	150 IU	500%
Thiamin (as thiamin mononitrate)	75 mg	5000%
Riboflavin	75 mg	4412%
Niacin (as niacinamide)	75 mg	375%
Choline (as choline chloride)	100 mg	*
Betaine (as betaine hydrochloride)	25 mg	*
Glutamic Acid (as L-glutamic acid)	25 mg	*
Inositol (as inositol monophosphate)	75 mg	*
para-Aminobenzoic acid	30 mg	*
Deoxyribonucleic acid	50 mg	*
Boron	500 mcg	*

* Daily Value not established

Other ingredients: Cellulose, stearic acid and silica.

Dietary supplement of an herb

Supplement Facts

Serving Size 1 Capsule

Amount Per Capsule	
Oriental Ginseng, powdered (root)	250 mcg*

* Daily Value not established.

Other ingredients: Gelatin, water, and glycerin.

A proprietary blend of dietary ingredients:

Supplement Facts

Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

1. Title, "Supplement Facts," will allow for easy identification.
2. Information must be listed "per serving." Serving sizes are determined by manufacturer's recommendations for consumption at one occasion.
3. Nutrients required in nutrition labeling of conventional foods must be listed when present and omitted when not present.
4. "Other dietary ingredients" (e.g., botanicals, phytochemicals) that do not have recommendations for daily consumption are listed beneath a bar. They are required to state the quantity present and to be identified as having no recommendations for consumption.
5. The list of dietary ingredients in the nutrition label (nutrients and non-nutrients) may include the source ingredient. If so, the source need not be listed again in the ingredient list.
6. Botanicals must state the part of the plant present and be identified by their common or usual name. In addition, their Latin binomial name is needed if the common or usual name is not listed in Herbs of Commerce published by the American Herbal Products Association.
7. Proprietary blends may be listed with the weight given for the total blend only. When this is done, components of the blend must be listed in descending order of predominance by weight.

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